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AUG 4 1995

James J. Schumann
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Re: Patent Term Extension
Application for
U.S. Patent No. 4,244,946

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,244,946 issued January 13, 1981, which claims the human drug product SUPPRELIN, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be two years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of June 2, 1992, as corrected in the Federal Register of April 14, 1994. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase)} + \text{Approval Phase} \\ &= \frac{1}{2} \text{ (1931)} + 947 \\ &= 1913 \text{ days}\end{aligned}$$

Since the regulatory review period began after the patent issue date, the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The two year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because: (1) the patent was issued before the date of enactment (September 24, 1984) of 35 U.S.C. § 156; (2) the date an exemption under subsection 505(i) of the Federal Food, Drug and Cosmetic Act involving the approved product became effective (February 8, 1984) was before the date of enactment; and (3) the date the new drug application was approved (December 24, 1991) was after the date of enactment. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed two years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for two years.

The 14 year exception of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the

absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of two years.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,244,946
Granted:	January 13, 1981
Applicant:	Jean E.F. Rivier et al.
Owner of Record:	The Salk Institute for Biological Studies
Title:	WATER-SOLUBLE PEPTIDES AFFECTING GONADAL FUNCTION
Classification:	424/177
Product Trade Name:	SUPPRELIN
Term Extended:	Two years

Gerald A. Dost
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Senior Legal Advisor
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(703) 305-9285

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

RE: SUPPRELIN
FDA Docket No.: 92E-0133